information but remain legally responsible for ensuring that the requirements of this section are met. The information must reflect changes in State law as soon as possible, but no later than 90 days after the effective date of the State law.

(ii) The M+C organization's written policies respecting the implementation of those rights, including a clear and precise statement of limitation if the M+C organization cannot implement an advance directive as a matter of conscience. At a minimum, this statement must do the following:

(A) Clarify any differences between institution-wide conscientious objections and those that may be raised by individual physicians.

(B) Identify the state legal authority permitting such objection.

(C) Describe the range of medical conditions or procedures affected by the conscience objection.

(D) Provide the information specified in paragraph (a)(1) of this section to each enrollee at the time of initial enrollment. If an enrollee is incapacitated at the time of initial enrollment and is unable to receive information (due to the incapacitating condition or a mental disorder) or articulate whether or not he or she has executed an advance directive, the M+C organization may give advance directive information to the enrollee's family or surrogate in the same manner that it issues other materials about policies and procedures to the family of the incapacitated enrollee or to a surrogate or other concerned persons in accordance with State law. The M+C organization is not relieved of its obligation to provide this information to the enrollee once he or she is no longer incapacitated or unable to receive such information. Follow-up procedures must be in place to ensure that the information is given to the individual directly at the appropriate time.

(E) Document in a prominent part of the individual's current medical record whether or not the individual has executed an advance directive.

(F) Not condition the provision of care or otherwise discriminate against an individual based on whether or not the individual has executed an advance directive.

(G) Ensure compliance with requirements of State law (whether statutory or recognized by the courts of the State) regarding advance directives.

(H) Provide for education of staff concerning its policies and procedures on advance directives.

(I) Provide for community education regarding advance directives that may include material required in paragraph (a)(1)(i) of this section, either directly or in concert with other providers or entities. Separate community education materials may be developed and used, at the discretion of the M+C organization. The same written materials are not required for all settings, but the material should define what constitutes an advance directive, emphasizing that an advance directive is designed to enhance an incapacitated individual's control over medical treatment, and describe applicable State law concerning advance directives. An M+C organization must be able to document its community education efforts.

(2) The M+C organization—

(i) Is not required to provide care that conflicts with an advance directive; and

(ii) Is not required to implement an advance directive if, as a matter of conscience, the M+C organization cannot implement an advance directive and State law allows any health care provider or any agent of the provider to conscientiously object.

(3) The M+C organization must inform individuals that complaints concerning noncompliance with the advance directive requirements may be filed with the State survey and certification agency.

§ 422.132 Protection against liability and loss of benefits.

Enrollees of M+C organizations are entitled to the protections specified in § 422.502(g).

Subpart D—Quality Assurance

SOURCE: 63 FR 35082, June 26, 1998, unless otherwise noted.

§ 422.152 Quality assessment and performance improvement program.

(a) *General rule.* Each M+C organization that offers one or more M+C plans must have, for each of those plans, an ongoing quality assessment and performance improvement program that meets the applicable requirements of this section for the services it furnishes to its M+C enrollees.

(b) *Requirements for network M+C MSA plans and M+C coordinated care plans other than PPO plans.* An organization offering a network M+C MSA plan or M+C coordinated care plan other than a PPO plan must do the following:

(1) Meet the requirements in paragraph (c)(1) of this section concerning performance measurement and reporting. With respect to an M+C coordinated care plan, an organization must also meet the requirements of paragraph (c)(2) of this section concerning the achievement of minimum performance levels. The requirements of paragraph (c)(2) of this section do not apply with respect to an M+C MSA plan.

(2) Conduct performance improvement projects as described in paragraph (d) of this section. These projects must achieve, through ongoing measurement and intervention, demonstrable and sustained improvement in significant aspects of clinical care and nonclinical care areas that can be expected to have a favorable effect on health outcomes and enrollee satisfaction.

(3) In processing requests for initial or continued authorization of services, follow written policies and procedures that reflect current standards of medical practice.

(4) Have in effect mechanisms to detect both underutilization and overutilization of services.

(5) Make available to HCFA information on quality and outcomes measures that will enable beneficiaries to compare health coverage options and select among them, as provided in § 422.64(c)(10).

(c) *Performance measurement and reporting.* The organization offering the plan must do the following:

(1) Measure performance under the plan, using standard measures required by HCFA, and report its performance to HCFA. The standard measures may be specified in uniform data collection and reporting instruments required by HCFA, and will relate to—

(i) Clinical areas including effectiveness of care, enrollee perception of care, and use of services; and

(ii) Nonclinical areas including access to and availability of services, appeals and grievances, and organizational characteristics.

(2) Achieve any minimum performance levels that HCFA establishes locally, regionally, or nationally with respect to the standard measures.

(i) In establishing minimum performance levels, HCFA considers historical plan and original Medicare performance data and trends.

(ii) HCFA establishes the minimum performance levels prospectively upon contract initiation and renewal.

(iii) The organization must meet the minimum performance levels by the end of the contract year.

(iv) In accordance with § 422.506, HCFA may decline to renew the organization's contract in the year that HCFA determines that it did not meet the minimum performance levels.

(d) *Performance improvement projects.* (1) Performance improvement projects are organization initiatives that focus on specified clinical and nonclinical areas and that involve the following:

(i) Measurement of performance.

(ii) System interventions, including the establishment or alteration of practice guidelines.

(iii) Improving performance.

(iv) Systematic follow-up on the effect of the interventions.

(2) Each project must address the entire population to which the measurement specified in paragraph (d)(1)(i) of this section is relevant.

(3) HCFA establishes M+C organization and M+C plan-specific obligations for the number and distribution of projects among the required clinical and nonclinical areas, in accordance with paragraphs (d)(4) and (d)(5) of this section, to ensure that the projects are representative of the entire spectrum of clinical and nonclinical care areas associated with a plan.

(4) The required clinical areas include:

(i) Prevention and care of acute and chronic conditions.

(ii) High-volume services.

(iii) High-risk services.

(iv) Continuity and coordination of care.

(5) The required nonclinical areas include:

(i) Appeals, grievances, and other complaints.

(ii) Access to, and availability of, services.

(6) In addition to requiring that the organization initiate its own performance improvement projects, HCFA may require that the organization—

(i) Conduct particular performance improvement projects that are specific to the organization; and

(ii) Participate in national or statewide performance improvement projects.

(7) For each project, the organization must assess performance under the plan using quality indicators that are—

(i) Objective, clearly and unambiguously defined, and based on current clinical knowledge or health services research; and

(ii) Capable of measuring outcomes such as changes in health status, functional status and enrollee satisfaction, or valid proxies of those outcomes.

(8) Performance assessment on the selected indicators must be based on systematic ongoing collection and analysis of valid and reliable data.

(9) Interventions must achieve improvement that is significant and sustained over time.

(10) The organization must report the status and results of each project to HCFA as requested.

(e) *Requirements for M+C PPO plans, non-network MSA plans, and M+C private fee-for-service plans.* An organization offering an M+C plan, non-network MSA plan, or private fee-for-service plan must do the following:

(1) Measure performance under the plan using standard measures required by HCFA and report its performance to HCFA. The standard measures may be specified in uniform data collection and reporting instruments required by HCFA and will relate to—

(i) Clinical areas including effectiveness of care, enrollee perception of care, and use of services; and

(ii) Nonclinical areas including access to and availability of services, appeals and grievances, and organizational characteristics.

(2) Evaluate the continuity and coordination of care furnished to enrollees.

(3) If the organization uses written protocols for utilization review, the organization must—

(i) Base those protocols on current standards of medical practice; and

(ii) Have mechanisms to evaluate utilization of services and to inform enrollees and providers of services of the results of the evaluation.

(f) *Requirements for all types of plans*—(1) *Health information.* For all types of plans that it offers, an organization must—

(i) Maintain a health information system that collects, analyzes, and integrates the data necessary to implement its quality assessment and performance improvement program;

(ii) Ensure that the information it receives from providers of services is reliable and complete; and

(iii) Make all collected information available to HCFA.

(2) *Program review.* For each plan, there must be in effect a process for formal evaluation, at least annually, of the impact and effectiveness of its quality assessment and performance improvement program.

(3) *Remedial action.* For each plan, the organization must correct all problems that come to its attention through internal surveillance, complaints, or other mechanisms.

[63 FR 35082, June 26, 1998, as amended at 65 FR 40323, June 29, 2000]

§ 422.154 External review.

(a) *Basic rule.* Except as provided in paragraph (c) of this section, each M+C organization must, for each M+C plan it operates, have an agreement with an independent quality review and improvement organization (review organization) approved by HCFA to perform functions of the type described in part 466 of this chapter.

(b) *Terms of the agreement.* The agreement must be consistent with HCFA guidelines and include the following provisions:

(1) Require that the organization—